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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE MERCK & CO., INC.
VYTORIN/ZETIA SECURITIES
LITIGATION

08-CV-2177 (DMC) (JAD)

IN RE SCHERING-PLOUGH
CORPORATION/ENHANCE
SECURITIES LITIGATION

08-CV-397 (DMC) (JAD)

**THE MERCK AND SCHERING DEFENDANTS' MEMORANDUM
OF LAW IN SUPPORT OF THEIR MOTION *IN LIMINE* NO. 6:
TO PRECLUDE PLAINTIFFS FROM OFFERING CERTAIN HEARSAY
AND IMPROPER OPINION TESTIMONY OF
MEREDITH GENE BOND**

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PRELIMINARY STATEMENT

During the course of the ENHANCE trial, Schering Plough Research Institute (“SPRI”), the entity directly overseeing the trial, consulted various independent scientists with expertise in intima-media thickness (“IMT”) imaging trials because SPRI had no prior experience conducting such trials. Meredith Gene Bond (“Bond”), Professor of Neurobiology and Anatomy at the Wake Forest University School of Medicine, and Director, Ultrasound Research, was one of the consultants who SPRI retained. Both Plaintiffs and Defendants have designated portions of Dr. Bond’s deposition testimony and have identified selected e-mails written by Dr. Bond as potential trial exhibits.

Defendants seek to exclude certain portions of Dr. Bond’s testimony (Bond Tr. 73:7-89:18), and an e-mail that he wrote in March 2007 (PTX 108), as unreliable hearsay that is improperly being offered for the truth of the matters asserted, and also because the contents constitute improper opinion testimony.

In this testimony and e-mail, Dr. Bond opines that an SPRI biostatistician, Dr. Bo Yang, may have “influenced” an unidentified CEL reader to declare certain images as “missing”, based not on anything that Dr. Bond personally witnessed, but based solely on a conversation that he had with Johann Gort, the chief sonographer of at the Core Echo Laboratory of the Department of Vascular Medicine in the Netherlands (“CEL”), which at the time was responsible

for reading and measuring the tens of thousands of ultrasound images of carotid arteries of the ENHANCE patients.

According to Dr. Bond, he learned from Johann Gort that Mr. Gort saw Dr. Yang stating to a reader at the CEL that if the reader could not accurately measure the ultrasound image, then the reader must declare the image “missing”. Based on this discussion with Mr. Gort, [REDACTED]

[REDACTED]

[REDACTED]

Dr. Bond’s recounting of Mr. Gort’s purported statements is classic hearsay that is being offered for its truth – that SPRI somehow “influenced” the CEL readers’ failures – and Dr. Bonds’ opinion is improper opinion testimony that is not based on any first-hand observations. Accordingly, the testimony and the e-mail should be precluded.

BACKGROUND FACTS

The ENHANCE clinical trial results depended on the accurate reading and measurement of the changes in the thickness of the carotid IMT of the 720 patients who were taking Vytorin or Zocor over a two-year period. It was the responsibility of the CEL readers in the Netherlands to accurately read and measure the tens of thousands of ultrasound images of carotid arteries that had been taken by sonographers. The CEL readers’ measurements were ultimately sent

to SPRI biostatisticians for further data quality testing to ensure reliability. (ENHANCE Clinical Study Protocol at 2364) (Second Affidavit of Robert N. Kravitz in Support of Defendants' Motions in Limine Nos. 1-7, sworn to February 1, 2013 ("Kravitz Aff. II") Ex. 44.) *See also* (Strony Dep. 143:14-144:18) (Kravitz Aff. II Ex. 45).

As the Medical Director overseeing the readers at the CEL acknowledged, over the course of the ENHANCE trial, the CEL readers failed to follow protocol, failed to provide measurements that were reliable or even appeared biologically plausible and that had to be re-read, and failed the quality-control assessments that were built into the study design. (*See* DTX 345, 475, 552) (Kravitz Aff. II Exs. 46-48.) Indeed, in the middle of the study, SPRI, with the full consent of the CEL and the principal investigator, Dr. John Kastelein, had to change the manner in which the CEL readers were reading and measuring the ultrasound images in order to improve the reliability of the measurements being generated by the CEL. (*See* DTX 1004 at 81-84) (Kravitz Aff. II Ex. 44 at 81-84.)

The difficulty experienced by the CEL readers in reading and measuring the ultrasound images is hardly surprising because they were measuring the tiniest part of the internal wall of a human carotid artery, which is smaller than the thickness of a human hair. The disputed question in this case is whether it was these and similar difficulties in the trial that led to the delay in the release of the

ENHANCE results, as Defendants contend, or whether the delay was based on intentional fraud, as Plaintiffs contend.

Prior to his retirement, Meredith Gene Bond was a professor of neurobiology and anatomy at the Wake Forest University School of Medicine, and director of its division of ultrasound research. (Bond Dep. 8:4-16; 10:9-14) (Kravitz Aff. II Ex. 49.) Dr. Bond is not a medical doctor, but has a Ph.D. in anatomy and pathology. (*Id.* at 9:8 – 10:2) (Kravitz Aff. II. Ex. 49.) SPRI retained Dr. Bond as a consultant for the ENHANCE trial because SPRI had never conducted an IMT imaging study like ENHANCE, and Dr. Bond served as a member of the Operations Committee responsible for overseeing CEL's work. (Strony Dep. 242:16 – 243:13) (Kravitz Aff. II Ex. 45.)

Dr. Bond testified by deposition on February 24, 2011. During the deposition, Dr. Bond was asked questions about a document identified as PX-108, which [REDACTED]

[REDACTED] (Kravitz Aff. II Ex. 50.) In his email, Dr. Bond stated:

[REDACTED]

[REDACTED]

(PX 108) (emphasis added).

In his deposition, Dr. Bond testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Bond Dep. 78:21 – 79:25; MSP-

CIVABY0069243 [REDACTED]) (Kravitz

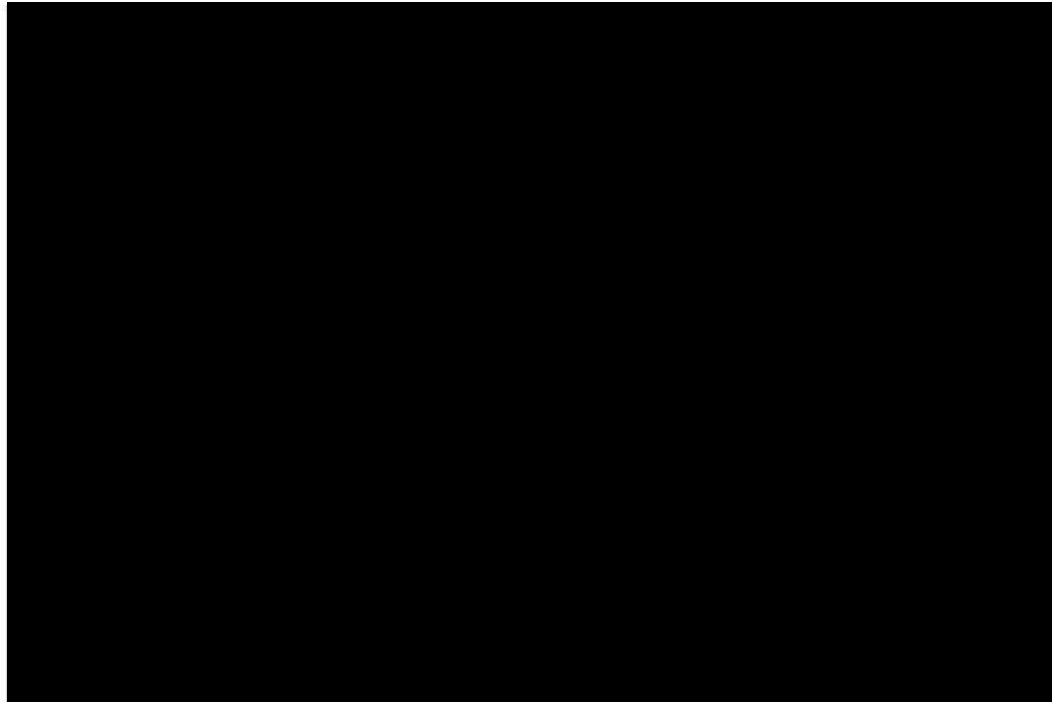
Aff. II Exs. 49 & 51) Dr. Bond said [REDACTED]

[REDACTED]


[REDACTED] (*Id.* at 80:17-22). [REDACTED]

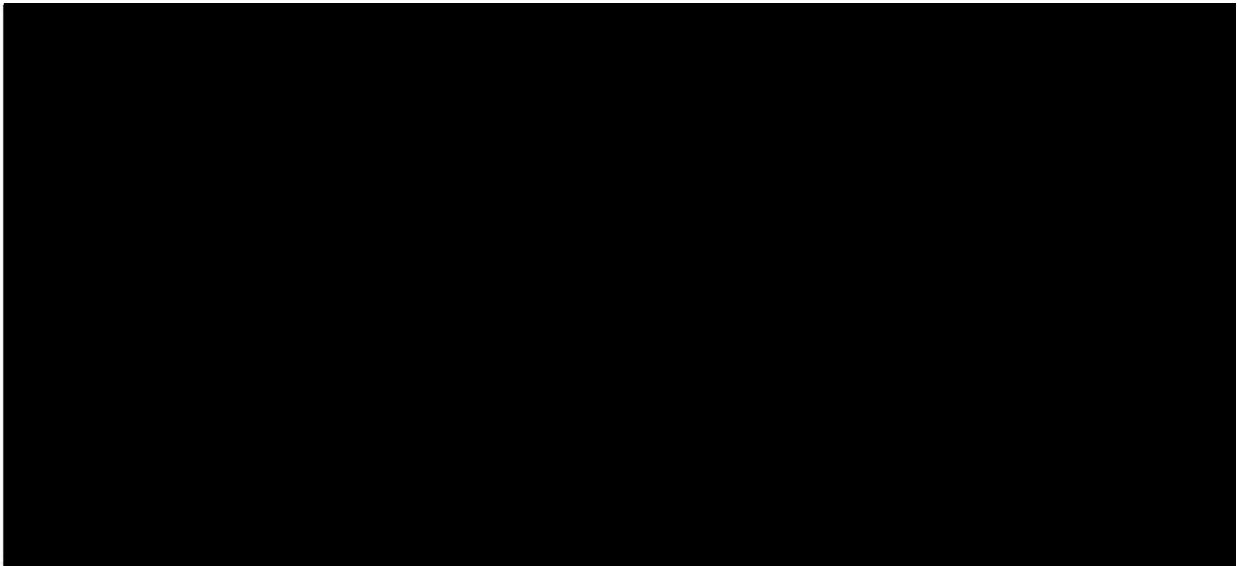
[REDACTED]


[REDACTED]




(Bond Dep. 83:17 – 84:16) (Kravitz Aff. II Ex. 49.)

Later in the deposition, Dr. Bond was asked whether 



(*Id.* 150:20 – 151:3.) 



 (*Id.* 151:3 – 153:15.)

Plaintiffs deposed Dr. Yang, but did not ask him any questions about such an incident. (Kravitz Aff. II ¶ 52.) Plaintiffs never sought the deposition of Mr. Gort.

ARGUMENT

I. The Court Should Preclude Dr. Bond's Testimony Concerning Johann Gort's Statements to Him as Inadmissible Hearsay

Dr. Bond's testimony concerning Mr. Gort's statements to him is classic hearsay.¹ Mr. Gort is not a witness at trial, yet his out-of-court statements are being offered by Plaintiffs for the truth of the matter asserted, that Dr. Yang influenced a reader at the CEL to declare certain images "missing".

Nor does any exception to the hearsay rule apply.

First, Mr. Gort's statements cannot be considered as a statement of a party opponent under Rule 801(d)(2)(D). Mr. Gort was not an employee of either Schering or Merck. He was a researcher at CEL, which was an independent laboratory hired to perform ultrasound readings in the ENHANCE trial. *See Conduis v. Howard Sav. Bank*, 986 F. Supp. 914, 916 (D. N.J. 1997) (in determining whether an independent contractor is an agent or non-agent, "the district court should assess whether the representatives are analogized better to a

¹ Under Rule 801(c) of the Federal Rules of Evidence, hearsay means "a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence to prove the truth of the matter asserted in the statement."

firm that contracts to perform a particular discrete task, such as to build a swimming pool, or to a party who is empowered to speak for another and bind the other in contracts.”)

Nor can Plaintiffs credibly argue that Mr. Gort’s statements do not go to the truth of the matter asserted, but rather to either Mr. Gort’s or Dr. Bond’s “state of mind.” In order to admit an otherwise hearsay statement on the ground that it goes to a person’s “state of mind,” the proponent must establish, among other things, that the person’s “state of mind” is relevant to the case.

See Canestri v. NYSA-ILA Pension Trust Fund & Plan, No. 07-1603, 2010 WL 4291489, at *1 (D. N.J. Oct. 22, 2010). Neither Mr. Gort nor Dr. Bond is a party to these cases, and the “state of mind” of neither of them has any relevance to either case.

Since Mr. Gort’s statements, as reported by Dr. Bond, are hearsay that are not subject to any exceptions, Dr. Bond should be precluded from testifying about them under Rule 802 of the Federal Rules of Evidence.²

² Rule 802 provides: “Hearsay is not admissible unless any of the following provides otherwise: a federal statute; these rules; or other rules prescribed by the Supreme Court.”

**II. The Court Should Preclude The Portion of PX-108
Relating to the Opinion that Dr. Bond Formed
Based Upon His Discussion with Mr. Gort**

Dr. Bond's statement in PTX-108 about his "opinion," which is based on nothing more than Mr. Gort's statements to him, should also be precluded. Dr. Bond has not been designated to testify as an expert. The only way his opinion testimony might arguably be admissible, therefore, would be as "lay opinion" under Rule 701, Fed. R. Evid.. Plaintiffs, however, have not identified Dr. Bond's testimony as lay opinion testimony in their pre-trial submissions, and his opinion does not meet the requirements for lay opinion testimony under Rule 701.

Rule 701 provides that, if a witness is not testifying as an expert, "testimony in the form of an opinion is limited to one that is: (a) rationally based on the witness's perception; (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701; *see also Hirst v. Inverness Hotel Corp.*, 544 F.3d 221, 225 (3d Cir. 2008) ("The plain language of Rule 701 establishes that lay opinion testimony must satisfy the criteria set forth in subsections (a), (b), *and* (c) in order to be admissible.") (emphasis in original).

The requirement that such testimony must be "rationally based on the witness's perception" means that it may not be based on hearsay. As this Court

held in *Blakey v. Continental Airlines, Inc.*, Civ. No. 93-2194 (WGB), 1997 U.S.

Dist. LEXIS 22074 (D. N.J. Sept. 15, 1997):

Unlike expert opinion testimony introduced pursuant to Rule 702, lay opinion testimony introduced pursuant to Rule 701 must be based on the personal knowledge of the witness. *Teen-Ed, Inc. v. Kimball International, Inc.*, 620 F.2d 399, 404 (3d Cir. 1980). “The requirement that lay opinion be based on the perception of the witness imports into Rule 701 the personal knowledge standard of Rule 602.” C. Wright & V. Gold, *Federal Practice and Procedure: Evidence*, § 6254 (1997). Therefore, “by restricting lay opinions to those based on the perception of the witness, the implication of Rule 701 is that lay opinion may not be based on hearsay.” *Id.*

Id. at *13; *see also TLT-Babcock, Inc. v. Emerson Elec. Co.*, 33 F.3d 397, 400 (4th Cir. 1994) (holding that trial court did not err in barring project manager from giving opinion as to what caused fan shafts to fail where his knowledge was based on reports from his staff and, thus, his opinion was not “based on the perception of the witness”); *U.S. v. Garcia*, 994 F.2d 1499, 1507 (10th Cir. 1993) (holding that Rule 701 requirement that lay opinion must be rationally based on the perception of the witness means the witness may offer opinions based on what he heard unless what he heard is excluded under the hearsay rules); *Hall v. C.I.A.*, 538 F. Supp. 2d 64, 69 (D. D.C. 2008) (“[I]f any third party statement could be admitted merely because it was heard (and ‘perceived’) by the witness, the entirety of hearsay jurisprudence would be nullified. It is clear that Rule 701 allows no such thing.”).

Nor can Plaintiffs justify Dr. Bond’s “opinion” as the admission of a party opponent under Rule 801(d)(2). Dr. Bond was not an employee or agent of

either Schering or Merck. He was an independent consultant. Indeed, his consulting agreement with SPRI itself states: [REDACTED]

[REDACTED] (Bond Consulting Agreement ¶ 12) (Kravitz Aff. II Ex. 52.) And Dr. Bond himself described his role as [REDACTED] (Bond Dep. 121:4-5) (Kravitz Aff. II Ex. 49.)

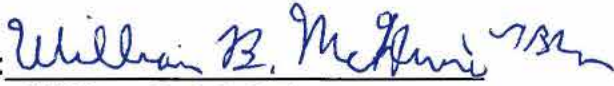
CONCLUSION

For the reasons set forth above, Plaintiffs should be precluded from offering Dr. Bond's deposition testimony about his conversation with Johann Gort and the opinion he formed based on that conversation, and from offering PTX-108.

Dated: February 1, 2013

Respectfully submitted,

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